



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,615	04/20/2007	Yuzuru Umeda	1691-0217PUS1	4241

2292 7590 03/30/2010  
BIRCH STEWART KOLASCH & BIRCH  
PO BOX 747  
FALLS CHURCH, VA 22040-0747

EXAMINER
----------

BASQUILL, SEAN M

ART UNIT	PAPER NUMBER
----------	--------------

1612

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

03/30/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/574,615	<b>Applicant(s)</b> UMEDA ET AL.	
	<b>Examiner</b> Sean Basquill	<b>Art Unit</b> 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 2-12, 15 and 16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-12, 15 and 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>27 Oct 2009</u> .   | 6) <input type="checkbox"/> Other: _____                          |

Art Unit: 1612

## **DETAILED ACTION**

### ***Previous Rejections***

1. Applicants' response, filed 27 October 2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### ***Status of the Claims***

2. Applicants' amendments to the Claims, filed with the response dated 27 October 2009, have been entered. Claims 1, 13, and 14 are cancelled, and Claims 2, 5-7, and 9 have been amended. Claims 2-12, 15, and 16 are presented for examination.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 2-12, 15, and 16 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,811,446 ( Thomas”), in view of U.S. Patent 5,994,372 (“Yaksh”), and U.S. Patent 5,116,868 (“Chen”), as put forth in the office action of 27 July, 2009.

Applicants arguments have been fully considered and are deemed unpersuasive. While it may be true that Thomas focuses attention on the treatment of posterior segment diseases such as glaucoma or macular degeneration, applicants are reminded that art is relevant art for all that it

Art Unit: 1612

not only particularly discloses, but would also reasonably suggest to the artisan possessing ordinary skill. MPEP § 2123. As such, the skilled artisan cannot overlook the explicit teaching of Thomas, indicating that the compositions therein described find utility in the treatment of, in addition to glaucoma or macular degeneration, topical diseases of the anterior segment of the eye including allergic conjunctivitis, viral conjunctivitis, and blepharitis, all of which manifest some form of tear abnormality as recited in the instant claims. Given this art-acknowledged utility, the examiner then proceeded to enunciate rationales as to why the skilled artisan would be motivated to include the ingredients described in Yaksh and Chen in the therapeutic compositions of Thomas being used to treat anterior segment ocular diseases such as allergic conjunctivitis, viral conjunctivitis, and blepharitis. The examiner, in making out his rationale, is not constrained to the identical rationale employed by the applicants in explaining the benefits or process which lead to the instant claimed invention. MPEP § 2144. Indeed, all that is required of the examiner in making out his *prima facie* case is "some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR International Co. v. Teleflex, Inc.*, 852 USPQ2d 1385, 1396 (U.S. 2007). As put forth in the previous action, Yaksh and Chen indicate that ketone bodies such as D,L-sodium-beta-hydroxy butyrate are known to treat inflammatory conditions of the eye, just as the compositions and methods of Thomas teach; the combination of elements known to address the same problem which perform nothing more than the art would expect them to perform is *prima facie* obvious. MPEP § 2144.06, *see also KSR* at 1395 ("the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results"). At this juncture, the burden has shifted to applicants to provide objective indicia of nonobviousness commensurate in scope with the

Art Unit: 1612

invention as claimed. Applicants have thus far have elected not to do so; unless and until such a time arrives, the rejection of record shall stand.

### ***Conclusion***

No Claims stand allowable.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean Basquill whose telephone number is (571) 270-5862. The examiner can normally be reached on Monday through Thursday, between 8AM and 6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1612

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sean Basquill  
Art Unit 1612

/JEFFREY S. LUNDGREN/  
Primary Examiner, Art Unit 1639